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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,730	04/14/2004	Sunghoon Kim	058333-0118	5013

22428 7590 01/28/2005

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,730	KIM ET AL.	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/17/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/930,169.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the action on the merits was received on 12/17/2004. Applicant amended claim 1 and the specification. Claim 1 is pending in the instant application. The sections of 35 U.S.C. not included in this office action can be found in a previous office action. An action on the merits follows.

Specification

The objection over the brief description of the drawings and the specification is maintained. While the applicant amended the specification to remove the description of the missing drawings 1-3 and amended the references to drawing 4 to refer to drawing 1, the application still contains drawings 2-4, which are duplicates of figure 1 and not described. Cancellation of drawings 2-4 overcomes this objection.

Drawings

Applicant's amended Figure 1 filed on 12/17/2004 is acceptable to the examiner. However, as stated above, the applicant is required to cancel figures 2-4 of the drawings.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/930,169, filed on 11/06/2001.

Information Disclosure Statement

Examiner has attached a copy of form SB-08 with reference A13 initialed.

Claim Rejections - 35 USC § 112

The rejection of amended claim 1 under 35 U.S.C 112, first paragraph for lack of enablement is maintained in part. Applicant's amendments and arguments have been fully considered but have not been found persuasive in fully overcoming the remaining grounds of rejection for reasons of record as discussed in detail below.

The previous office action identified the following issues of record: 1) lack of enablement for an enhancement of any type of immune response; 2) lack of enabling disclosure for any cell or tissue; and 3) lack of enablement for *in vivo* methods. Applicant's amendments to the claims have overcome the rejection based on issue 1.

Applicant has amended claim 1 to read on a "method of inducing production of IL-8 and TNF...to a cell in need thereof." This amendment overcomes issue 1 as stated above. However, Applicant argues that it is well known in the art that IL-8 and TNF are effective regulators of the immune system and that the restriction requirement of the present claim is improper. Since a restriction requirement was never made in this application, it is presumed that applicant is arguing the scope of enablement of claim 1 set forth in the previous action. To wit, that applicant was not enabled for an enhancement of any type of immune response. Applicant argues that IL-8 and TNF are known effective regulators of the immune system, and cites Schroder et al. The examiner acknowledges that Schroder et al. discusses the effects of IL-8 and TNF on human dermal fibroblasts in culture. However, Schroder et al. does not contemplate or discuss any affects associated with the administration of the polypeptides of SEQ ID NO: 1 or NO: 2 *in vivo* or *in vitro.* Applicant's invention reads on a method of treating cells with the polypeptides of SEQ ID NO: 1 or NO: 2. The specification does not contemplate or

describe the direct administration of TNF or IL-18 to any cells *in vitro* or *in vivo*. Further, as stated in the previous office action the polypeptides of SEQ ID NO: 1 or NO: 2 are not known to induce any and all immune responses. The same holds true for IL-8 and TNF; they are not known to enhance any and all immune response, such as histamine release, isotope switching or the induction of TH3 T cells. Applicant has not demonstrated that administration of the polypeptides of SEQ ID NO: 1 or NO: 2 to a cell can enhance any and all immune responses. However, since applicant has amended claim 1 so that the method reads solely on the induction of IL-8 and TNF in a cell after administration of the polypeptides of SEQ ID NO: 1 or NO: 2 to a cell, rejection 1 is withdrawn.

The rejections of record based on issues 2 and 3 are so closely related they will be treated together. The rejection based on issue 2 is maintained in part and the rejection based on issue 3 is maintained in full. Claim 1 was amended so that the method no longer reads on administration to a tissue. However, claim 1 continues to read on administration to any cell. The specification does not teach administration of the polypeptides of SEQ ID NO: 1 or NO: 2 to any other cells than THP-1 cells, see previous action for further details. Applicant cites Cassatella et al. in support of their argument. However, while Cassatella et al. teaches that human polymorphonuclear leukocytes can produce IL-8 after treatment with FMLP, *in vitro*, Cassatella et al. does not teach that human polymorphonuclear leukocytes can produce IL-8 or TNF after treatment with the polypeptides of SEQ ID NO: 1 or NO: 2. The specification only teaches that a monocytic leukemia cell line (such as THp-1) can produce TNF or IL-8 after treatment with the polypeptides of SEQ ID NO: 1 or NO: 2, *in vitro*. As discussed in the previous office it is unpredictable to extrapolate results observed from *in vitro* studies with cancerous cell

lines to *in vivo* applications. The specification does not teach that the polypeptides of SEQ ID NO: 1 or NO: 2 can induce IL-8 or TNF from any cell *in vitro*. For these reasons of record and those stated in the previous action the rejection over issue 2 is maintained.

Further, applicant argues that the attached experimental data has bearing on macrophage production. Applicant's data shows evidence of increased numbers of macrophages in a mouse model after wounding. According to the experimental design p43+/+ and p43 -/- mice were wounded, with subsequent fixation and comparison of the wounded tissue. However, applicant does not disclose that the polypeptides of SEQ ID NO: 1 or NO: 2 were applied or that even an exogenous p43 peptide was applied. No evidence of IL-8 or TNF production is presented from the mouse model. Further the attached experimental data shows three slides, one of which purports to show WT+p43 skin, which is presumed to be from the p43+/+ mouse (but since the figure labels do not correspond with the experimental method terminology, it is difficult to be sure). The WT+ p43 skin shows the highest number of macrophages in comparison to the other two slides. However, it is unclear what this represents. Since the experiment does not indicate that any exogenous compounds were applied to the mice in question, or what the time frame was between the wounding and the fixation of the wound; it is impossible to determine whether the differences in the observed number of macrophages is due to differences in migration due to the different genetic backgrounds or differences in macrophage proliferation due to the different genetic backgrounds. In any event, this data is not considered to be persuasive evidence that the polypeptides of SEQ ID NO: 1 or NO: 2 can induce IL-8 or TNF from any cell *in vitro* or *in vivo*.

Applicant argues that the specification shows on page 15 that the polypeptide of the present invention can induce IL-8 and TNF. Examiner agrees that applicant has shown that the polypeptides of SEQ ID NO: 1 or NO: 2 can induce IL-8 or TNF from a monocytic leukemia cell line *in vitro*. However, as stated above and in the previous office action theses results are not considered to be persuasive evidence that the polypeptides of SEQ ID NO: 1 or NO: 2 can induce IL-8 or TNF from any cell *in vivo*. Further, applicant cites YG et al., published in 2001, in support of his arguments. Applicant states that YG et al. was supplied as A13 on form SB-08. However, a review of the information disclosure form indicates that A13 is actually Park et al., which was published in 1999. Since, applicant did not provide a copy of the relevant article with his response, and since it cannot be determined that the article by YG et al. was provided in the parent application, applicant's arguments in regards to this article were not considered. For these reasons of record and those stated in the previous action the rejection over issue 3 is maintained.

Double Patenting

Applicant states that since they did not file a response to the non-final rejection for Application No. 09/930,169, mailed on 1/14/2004, and therefore it is abandoned. However, a review of the relevant application reveals that it is still listed in active status by the Office. Since applicant did not include a copy of the notice of abandonment for Application No. 09/930,169, with their response to the previous office action of the instant application this argument is not considered persuasive. The double patenting rejection over Application No. 09/930,169 is therefore maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (571)-272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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